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10/024,040	12/21/2001	David S. Garvey	102258.326 US2	5280

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/024,040

**Applicant(s)**

GARVEY ET AL.

**Examiner**

Raymond J Henley III

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**CLAIMS 13 AND 16-19 ARE PRESENTED FOR EXAMINATION**

Applicants' After-Final Amendment filed May 5, 2004 has been received and entered into the application. Accordingly, the specification at page 1 and claim 13 have been amended and claims 14 and 15 have been canceled.

In view thereof, all issues raised in the Final Office action dated February 12, 2004 are withdrawn.

***Withdrawal of Finality***

The finality of the previous Office action is withdrawn so that new reference may be applied to the pending claims.

***Comments Regarding Interfering Subject Matter***

The Examiner indicated in the previous Office action that certain of applicants' claims would be placed into interference with certain claims of U.S. Patent Nos. 6,306,841, 6,165,975 and 6,031,002.

In light of applicants' amendment to present claim 13, in which the administration is limited to nasal or oral, the same patentable invention no longer exists in the present application and the claims of either of the '841 or '002 patent, in each of which, administration is limited to direct application to the female genitalia.

Respecting the '975 patent, upon review thereof, it is seen that its effective filing date is June 23, 1997 which is before the effective filing date of the present application, i.e., October 31, 1997. Accordingly, the '975 patent will be applied against the present claims under 35 U.S.C. 102 and/or 103 herein.

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***Double Patenting***

**Non-Provisional**

*I* Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 8-10, 16 and 17 of U.S. Patent No. 5,958,926 (cited by Applicants on January 26, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite “comprising” and thus do not exclude the nitrosated or nitrosylated phosphodiesterase inhibitor of the patented claims which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

*II* Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7, 8 and 9 of U.S. Patent No. 6,133,272 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite “comprising” and thus do not exclude the compound having the structure X in patented claim 3 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

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**III** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24 and 29-31 of U.S. Patent No.

6,172,060 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the compound having the structure I in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of a sexual dysfunction. Also, while the patented claims are silent as to the sex of the individual and the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to a sexual dysfunction in an individual in general and thus would have encompassed such a dysfunction of any origin in both male and female individuals.

**IV** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 and 29-31 of U.S. Patent No.

6,172,068 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the phosphodiesterase inhibitors in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**V** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 and 29-31 of U.S. Patent No.

6,177,428 (newly cited by the Examiner). Although the conflicting claims are not identical, they

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are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the phosphodiesterase inhibitors of structure IV in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**VI** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 and 29-31 of U.S. Patent No. 6,197,778 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the compound of structure II in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**VII** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 and 29-31 of U.S. Patent No. 6,197,782 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the phosphodiesterase inhibitors in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of

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the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**VIII** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-6 of U.S. Patent No. 6,211,179 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite “comprising” and thus do not exclude the phosphodiesterase inhibitors in patented claim 1 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of a sexual dysfunction. Also, while the patented claims are silent as to the sex of the individual and the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to a sexual dysfunction in an individual in general and thus would have encompassed such a dysfunction of any origin in both male and female individuals.

**IX** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 25 and 29-31 of U.S. Patent No. 6,232,321 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite “comprising” and thus do not exclude the phosphodiesterase inhibitors of structure VIII in patented claim 24 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

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**X** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 27 and 31-33 of U.S. Patent No. 6,316,457 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the phosphodiesterase inhibitors in patented claim 25 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**XI** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46, 47, 53 and 57-59 of U.S. Patent No. 6,462,044 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the phosphodiesterase inhibitors in patented claim 46 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

**XII** Claims 13 and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 9, 10, 16 and 17 of U.S. Reissued Patent No. 37,234 (newly cited by the Examiner). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims



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recite "comprising" and thus do not exclude the compound of patented claim 1 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the sex of the individual and the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to a sexual dysfunction in an individual in general and thus would have encompassed such a dysfunction of any origin in both male and female individuals.

**Provisional**

Claims 13 and 16-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 18-21, 26, 27 and 29 of copending Application No. 10/216,886. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims recite "comprising" and thus do not exclude the compound of co-pending application claim 1 which is co-administered with the presently claimed S-nitrothiol compounds for the treatment of female sexual dysfunction. Also, while the patented claims are silent as to the specific origin of the sexual dysfunction as in present claim 16, the patented claims nevertheless are directed to sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### ***Claim Rejection - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (U.S. Patent No. 6,165,975, cited by the Examiner on July 3, 2003) who teach the treatment of a vascular condition associated with a female sexual dysfunction which comprises orally or nasally administering to a female individual a S-nitrosothiol compound which may be S-nitrosoglutathione or S,S-dinitrosodithiol (see col. 7, lines 44 and 45, col. 15, line 3 and cols. 19 and 20, claims 1, 7, 8 and 14).

### ***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (as relied upon above) in view of Stamler et al. (U.S. Patent No. 5,380,758, cited by Applicants on January 26, 2004).

The differences between the above and the claimed subject matter lie in that Adams et al. fails to highlight:

(1) S-nitrosothiols other than S-nitrosoglutathione or S,S-dinitrosodithiol which are presently claimed; and

(2) the specific origins of the sexual dysfunction as presently claimed.

However, to the skilled artisan, the claimed subject matter would have been obvious because Adams et al. teach the use of the S-nitrosothiols because they are nitric oxide donors (col. 7, lines 33-38) while Stamler et al. teach that other nitrosothiols including S-nitroso-N-acetylcysteine, S-nitroso-captopril, S-nitroso-homocysteine, S-nitroso-cysteine and those of present claim 19 (col. 3, line 46 – col. 4, line 10) have a significant advantage in that they deliver nitric oxide (a.k.a. NO) in its most biologically relevant and non-toxic form (col. 7, lines 60-62). The skilled artisan would have been motivated to employ the S-nitrosothiols of Stamler et al. in the manner taught by Adams et al. because Adams et al. teach that the S-nitrosothiols are useful because they donate NO and Stamler et al. teach that the presently claimed S-nitrosothiols are not only NO donors, but also deliver NO in its most biologically relevant and non-toxic form. Also, Adams et al. teach sexual dysfunction in general and thus would have encompassed such a dysfunction of any origin.


Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

May 14, 2004